RML REGIONAL MEDICAL LABORATORY, INC.

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August 16, 1999

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Documents Branch
Food & Drug Administration
5630 Fishers Lane, #1061
Rockville, MD 20852

Dear Sirs:

As a member of the laboratory staff at St. John Medical Center in Tulsa, Oklahoma, I am writing to you in regards to a draft guidance document (HFA-305) that proposes expanding the current HCV Lookback Program beyond July of 1992 to May of 1990, thus incorporating donor results from the first generation screening test for Hepatitis C. This single antigen screening assay was implemented in 1990 as the best method to protect the nation's blood supply. The assay had a very high false positive rate, up to 40% in the experience of our local blood collection center, but was acceptable in keeping with the mission of a blood collection agency, to screen out as many potentially infected units of blood as possible. Such a high false positive rate would not be acceptable for a purely diagnostic test.

Retrospective HCV Lookback using multiantigen screening assay results for HCV, back to when first implemented in July of 1992, is still ongoing. Locally, our blood collection agency has completed retrospective lookback through only approximately 25% of their donor records. Consequently, the bulk of the retrospective lookback and physician or recipient notification is still before us, although within the specified time period outlined in the Guidance for Industry published in September of 1998. This lookback initiative has required a tremendous effort on the part of blood collection agencies and consignee hospital transfusion services.

It is with some concern that I learn of the proposed extension of HCV retrospective lookback, to include the first generation screening test that has a high false positive rate, thus identifying many donors who were, in fact, negative for HCV. A further cause for concern is the requirement that providers "search historical records dating back indefinitely to the extent that electronics or other readily retrievable records exist." This would be a cumbersome, costly and inefficient approach.

A far better approach would be to urge all patients transfused prior to July of 1992, as well as those individuals with other risk factors for contracting hepatitis C, such as percutaneous blood or body fluid exposure, to be tested using current screening assays for HCV. This would be a far more effective way to address this important public health issue.

As such, the extension of the lookback process through 1990 does not appear justified. I urge you to reconsider this draft proposal, and maintain the lookback initiative as currently written in the Guidance for Industry published in September of 1998. Encouragement of universal screening for HCV would be preferable, both for those who have been transfused before July 1992 as well as for those who have other risk factors.

Thank you for your consideration of these issues.

Sincerely yours,

Brent D. Hartsell, M.D.

BDH:sm

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